

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

DONNA BOOKER, on behalf of
deceased Raissa Booker,

Plaintiff,

Case No. 3:12 oe 40000

-vs-

MEMORANDUM OPINION

JOHNSON & JOHNSON,

Defendant.

KATZ, J.

Decedent Raissa Booker experienced bilateral pulmonary emboli after using Defendants' Ortho Evra® birth control patch. Decedent was a minor at the time of her injury and death. Decedent's mother, Plaintiff Donna Booker, therefore sued Defendants on Decedent's behalf. Currently pending is Defendants' combined motion for summary judgment and judgment on the pleadings. (Doc. 6). For the reasons that follow, Defendants' motion is granted in part and denied in part..

I. Background

Decedent was a Georgia resident and was prescribed the Ortho Evra® birth control patch in March 2010 by Dr. Elizabeth W. Killebrew, M.D., a Georgia Board-certified OB/GYN. The record reflects that at the time Dr. Killebrew prescribed the patch to Decedent, she was informed of Ortho Evra®'s risks and was familiar with Ortho Evra®'s September 2009 package insert, which specifically warned of, *inter alia*, increased risk of blood clots and pulmonary embolism. Further, Dr. Killebrew testified that she prescribed Ortho Evra® for Plaintiff because she believed its benefits outweighed its risks.

Decedent used Ortho Evra® from October 2009 until March 2010 when she experienced bilateral pulmonary emboli and passed away. Plaintiff subsequently filed this action as part of the Ortho Evra® multidistrict litigation. Defendants now move for summary judgment and judgment on the pleadings.

II. Legal Standards

A. Summary Judgment

Summary judgment is appropriate where “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The moving party bears the initial responsibility of “informing the district court of the basis for its motion, and identifying those portions of ‘the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,’ which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553, 91 L. Ed. 2d 265 (1986). The movant may meet this burden by demonstrating the absence of evidence supporting one or more essential elements of the non-movant’s claim. *Id.* at 323-25. Once the movant meets this burden, the opposing party “must set forth specific facts showing that there is a genuine issue for trial.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250, 106 S. Ct. 2505, 2541, 91 L. Ed. 2d 202 (1986) (quoting FED. R. CIV. P. 56(e)).

Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient “simply [to] show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus.*

Co. v. Zenith Radio Corp., 475 U.S. 574, 586, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986). Rather, Rule 56(e) “requires the nonmoving party to go beyond the pleadings” and present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324, 106 S. Ct. at 2553; *see also Harris v. General Motors Corp.*, 201 F.3d 800, 802 (6th Cir. 2000). Summary judgment must be entered “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex*, 477 U.S. at 322, 106 S. Ct. at 2552.

“In considering a motion for summary judgment, the Court must view the facts and draw all reasonable inferences therefrom in a light most favorable to the nonmoving party.” *Williams v. Belknap*, 154 F. Supp. 2d 1069, 1071 (E.D. Mich. 2001) (citing *60 Ivy Street Corp. v. Alexander*, 822 F.2d 1432, 1435 (6th Cir. 1987)). However, “at the summary judgment stage the judge’s function is not himself to weigh the evidence and determine the truth of the matter,”” *Wiley v. U.S.*, 20 F.3d 222, 227 (6th Cir. 1994) (quoting *Anderson*, 477 U.S. at 249); therefore, “[t]he Court is not required or permitted . . . to judge the evidence or make findings of fact.” *Williams*, 154 F. Supp. 2d at 1071. The purpose of summary judgment “is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried.” *Abercrombie & Fitch Stores, Inc. v. Am. Eagle Outfitters, Inc.*, 130 F. Supp. 2d 928, 930 (S.D. Ohio 1999). Ultimately, this Court must determine “whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.” *Anderson*, 477 U.S. at 251-52; *see also Atchley v. RK Co.*, 224 F.3d 537, 539 (6th Cir. 2000).

B. Judgment on the Pleadings

The Court construes Plaintiff's motion to dismiss as a Fed. R. Civ. P. 12(c) motion for judgment on the pleadings.

A Fed. R. Civ. P. 12(c) motion for judgment on the pleadings is analyzed under the same standard as a Fed. R. Civ. P. 12(b)(6) motion to dismiss. *Sensations, Inc. v. City of Grand Rapids*, 526 F.3d 291, 295 (6th Cir. 2008). To defeat such a motion, the complaint must state sufficient facts, accepted as true, to state a claim "that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In deciding the motion, the Court must accept as true all of the non-movant's factual allegations. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Thurman v. Pfizer, Inc.*, 484 F.3d 855, 859 (6th Cir. 2013). The complaint "need not contain 'detailed' factual allegations, [but] its 'factual allegations must be enough to raise a right to relief above the speculative level . . .'" *Ass'n of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 548 (6th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Conclusory allegations and legal conclusions masquerading as factual allegations will not suffice. *Twombly*, 550 U.S. at 555 (holding that a complaint must contain more than "a formulaic recitation of the elements of the cause of action").

III. Discussion

A. Summary Judgment on Failure to Warn

Defendants move for summary judgment against Plaintiff's failure to warn claims. Defendants argue the claims are bared by Georgia's learned intermediary doctrine because Decedent's physician, Dr. Killebrew, was fully apprised of the risks associated with Ortho Evra® when she prescribed the drug for Decedent.

Georgia has adopted the learned intermediary doctrine, which modifies a prescription drug manufacturer's duty to warn of the drug's dangerous propensities:

Under the learned intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer. The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the ““decision to employ prescription medication [or medical devices] involves professional assessment of medical risks in light of the physician’s knowledge of a patient’s particular need and susceptibilities.””

McCombs v. Synthes, 587 S.E.2d 594, 595 (Ga. 2003) (quoting *McCombs v. Synthes*, 553 S.E.2d 17, 20 (Ga. Ct. App. 2001)). Importantly, a manufacturer's warning must be adequate to satisfy the learned intermediary doctrine. *Id.* Adequacy of a warning may be determined as a matter of law. See *McCombs v. Synthes*, 596 S.E.2d 780, 780 (Ga. Ct. App. 2004) (citations omitted) (“We conclude, as did the trial court, that under the learned intermediary doctrine, this warning to Dr. Acheclar was adequate and reasonable under the circumstances of her case.”); see also *Wheat v. Sofamor, S.N.C.*, 46 F.Supp.2d 1351, 1363 (N.D. Ga. 1999) (citations omitted) (“As a threshold issue, the Court should determine whether an adequate warning was given to Plaintiffs’ physician.”).

In the instant matter, Georgia's learned intermediary doctrine entitles Defendants to summary judgment on Plaintiff's failure to warn claims. Dr. Killebrew was aware of Ortho Evra®'s increased risk of blood clots and pulmonary embolism when she prescribed the drug to Decedent. Dr. Killebrew testified that she nevertheless prescribed Ortho Evra® for Plaintiff because she believed its benefits outweighed its risks. Further, Defendants' September 2009 Ortho Evra® warnings were adequate as a matter of law in this case because they warned of the specific adverse event suffered by Plaintiff; namely pulmonary embolism. Plaintiff claims

Defendants' warnings were inadequate because they did not incorporate certain language from a FDA study published in 2011. Yet, Georgia law only requires a manufacturer to warn of those dangers about which the manufacturer has actual or constructive knowledge. *Hunter v. Werner Co.*, 574 S.E.2d 426, 431 (Ga. Ct. App. 2002). Plaintiff offers no evidence suggesting Defendants had actual or constructive knowledge of the 2011 FDA study when they issued their September 2009 Ortho Evra® warning, or when Dr. Killebrew prescribed Ortho Evra® to Decedent in October 2009. Thus, there are no issues as to the adequacy of Defendants' warning in this case, and Defendants are entitled to summary judgment on Plaintiff's failure to warn claims.

C. Judgment on the Pleadings

Defendants move for Fed. R. Civ. P. 12(c) judgment on the pleadings against Plaintiff's sundry negligence and fraud claims, as well as against Plaintiff's breach of express and implied warranty, design defect, manufacturing defect, and intentional infliction of emotional distress claims.¹

Regarding negligence, fraud, and breach of warranty, Defendant correctly argues that Georgia's learned intermediary doctrine bars these claims. *See Catlett v. Wyeth, Inc.*, 379 F.Supp.2d 1374, 1381 (M.D. Ga. 2004) ("It is clear that Georgia courts would find the 'learned intermediary rule' encompasses any fraud, fraudulent concealment, misrepresentation, failure to warn or breach of warranty claims related to the sale and use of prescription drugs."); *accord Lee*

¹

The section heading in Defendants' brief purports to move for Fed. R. Civ. P. 12(c) judgment on the pleadings against all of Plaintiff's remaining claims. (Defs.' Br. Supp. Mo., Doc. 6-9 at 14). Yet, the body of Defendants' brief only makes Rule 12(c) arguments against specific claims, leaving other claims (e.g., loss of consortium), un-argued. (See Abbreviated Short Form Compl., Doc. 1 at PageID #: 5) (asserting claim for Loss of Consortium). The instant opinion only addresses those claims that Defendant specifically argues in the body of their brief.

v. Mylan, Inc., 806 F.Supp.2d 1320, 1324 (M.D. Ga. 2011) (citing *id.*) (Georgia's learned intermediary doctrine "encompasses any claim based upon the failure of the manufacturer to provide the patient with correct or necessary information concerning the use of the product."). Importantly, the Court will treat Defendants' motion for judgment on the pleadings against these claims as a motion for summary judgment because, as discussed above, the learned intermediary analysis requires consideration of evidence. *See Fed. R. Civ. P. 12(d)* ("If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56."). Both sides have had reasonable opportunities to argue the evidence and present all pertinent materials, and Defendants' motion for summary judgment against Plaintiff's negligence, breach of warranty, and fraud claims will therefore be granted for the same reasons stated in the learned intermediary analysis, *supra*. *See id.* (where 12(b)(6) or 12(c) motion treated as summary judgment motion, "[a]ll parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.").

Defendants' motion for judgment on the pleadings against Plaintiff's design defect, manufacturing defect, and intentional infliction of emotional distress claims will be denied. Contrary to Defendants' assertions, Plaintiff pleads the existence of a feasible alternative design. (*See* Ortho Evra Prods. Liab. Master Compl., Doc. 7-6 at ¶ 105). Plaintiff also alleges product deviations resulting in a manufacturing defect. (*Id.* at ¶¶ 108-110). Finally, Plaintiff pleads extreme conduct to support an intentional infliction of emotional distress claim. (*Id.* at ¶¶ 69-71, 273). As such, Defendants' motion for judgment on the pleadings against Plaintiff's design

defect, manufacturing defect, and intentional infliction of emotional distress claims will be denied.²

IV. Conclusion

For the reasons stated herein, Defendants' motion for summary judgment against Plaintiff's failure to warn, negligence, breach of warranty and fraud claims is granted. (Doc. 6).

Further, Defendants' motion for judgment on the pleadings is denied. (Doc. 6).

IT IS SO ORDERED.

s/ David A. Katz
DAVID A. KATZ
U. S. DISTRICT JUDGE

²Defendants' Rule 12(c) arguments against manufacturing defect and intentional infliction of emotional distress conspicuously make passing references to a lack of evidence. (Defs.' Br. Supp. Mo., Doc. 6-9 at 16-18). Despite this, it is clear the gravamen of Defendants' argument is made pursuant to Rule 12(c), not Rule 56. In any event, the nature of the briefs have not afforded Plaintiff proper notice to introduce pertinent materials and to make summary judgment arguments as to these claims. Accordingly, Defendants' manufacturing defect and intentional infliction of emotional distress arguments will be treated as Rule 12(c) arguments. See Fed. R. Civ. P. 12(d).